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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,431	07/18/2003	Jay D. Kranzler	CYPR 100 CIP CON	4067
7278	7590	08/19/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,431

Applicant(s)

KRANZLER ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-49,56-65 and 71-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-49,56-65 and 71-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 50-55 and 66(sic)-70 have been cancelled by the amendment of June 10, 2005.

Claims 26-49, 56-65 and 71-75 are pending and examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28-29, 32-33, 35, 39-41, 43, 47-48, 56, 58, 60, 61, 63, 65-66, 70-71, 73, 75 are again rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/32178. WO 00/32178 (page 1, line 15, page 6, line 15 through page 7, line 5, page 30, line 9) discloses a method of using a SNRI to treat pain of CFS and FMS using sibutramine. Some dependent claims appear to differ over WO 00/32178 in reciting that the SNRI has NMDA receptor antagonistic properties. However, it would be inherent that a compound that yields the instant method has said properties.

Applicants argue that sibutramine is not a SNRI as defined in the specification, but is a triple reuptake inhibitor. This is not persuasive. It would be inherent that since the instant compound yields the method of WO 00/32178 that it also inhibits the reuptake of dopamine.

Claims 26, 28, 61, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Ninan. Ninan (abstract) discloses that venlafaxine, a SNRI compound, is useful to treat symptoms of fibromyalgia and chronic pain. Ninan does not disclose that venlafaxine inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin or that it has NMDA receptor antagonistic properties. However, it would be inherent that a compound that yields the instant method inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties.

Claims 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by MEDLINE AN 2001337451.

MEDLINE AN 2001337451 (abstract) discloses that venlafaxine, a SNRI compound, is useful to treat chronic pain. MEDLINE AN 2001337451 does not disclose that venlafaxine inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin or that it has NMDA receptor antagonistic properties. However, it would be inherent that a compound that yields the instant method inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties.

Claims 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by MEDLINE AN 97363915 or MEDLINE AN 97229930.

MEDLINE 97363915 (abstract) and MEDLINE AN 97229930 disclose that tramadol, a SNRI compound, is useful to treat chronic pain. The references do not disclose that tramadol inhibits NE reuptake to an equal or greater extent than it inhibits

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the reuptake of serotonin or that it has NMDA receptor antagonistic properties.

However, it would be inherent that a compound that yields the instant method inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties.

Claims 61 and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by Enggaard.

Enggaard (abstract) discloses that venlafaxine, a SNRI compound, is useful to treat symptoms of fibromyalgia and chronic pain. Enggaard does not disclose that venlafaxine inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin or that it has NMDA receptor antagonistic properties. However, it would be inherent that a compound that yields the instant method inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 28-35, 37-43, 45-50, 56, 58-61, 63-66, 68-71, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ninan in view of WO 00/32178.

Ninan (abstract) discloses that venlafaxine, a SNRI compound, is useful to treat symptoms of fibromyalgia and chronic pain. Ninan does not disclose that venlafaxine inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties, that it is administered adjunctively with a second compound, that or that it is formulated in a sustained release dosage formulation.

However, WO 00/32178 (page 1, line 15, page 6, line 15 through page 7, line 5, page 30, line 9) discloses a method of using a sibutramine to treat pain of CFS and FMS.

However, it would be inherent that a compound that yields the instant method inhibits NE reuptake to an equal or greater extent than it inhibits the reuptake of serotonin, that it has NMDA receptor antagonistic properties.

Furthermore, it would be obvious to combine sibutramine with venlafaxine to treat pain or other symptoms of CFS or FMS, since they are both used in the art to ameliorate said pain and other symptoms. Moreover, no unobviousness is seen in using a sustained release dosage formulation, since it is conventional and known in the art.

In view of Applicants' argument the earlier rejection of WO 00/32178 in view of Ninan is withdrawn, thereby mooted Applicants' arguments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-49, 56-65 and 71-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,602,911 and copending Application No. 10/623,378 for the reasons given in the Paper of September 29, 2004. The "comprising" of '911 and '378 would allow for the second compound of newly submitted claims 76-93.

The terminal disclaimers filed on June 10, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,602,911 and copending Application No. 10/623,378 have been reviewed and is NOT accepted.

The terminal disclaimers do not indicate the "percent" interest the maker of the terminal disclaimers has in the application. The interest must total 100%. No percentage is given in any of them.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', written in a cursive style.

Primary Examiner
Art Unit 1614

August 15, 2005